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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

WOCKHARDT USA LLC; and
WOCKHARDT LTD.,

and

SUN PHARMA GLOBAL FZE and SUN
PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendants.

Civil Action No. 12-3967
(SDW)(MCA)
(Consolidated with Civil Action Nos.
12-4393, 13-1028 and 13-2379)

DEFENDANTS' SUBMISSION OF
SUPPLEMENTAL AUTHORITY IN
SUPPORT OF THEIR MOTION TO
DISMISS COUNT II OF THE
CORRECTED AMENDED
COMPLAINT

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.;
APOTEX CORP.; GLAND PHARMA
LTD.; DR. REDDY'S
LABORATORIES, INC.; DR.
REDDY'S LABORATORIES LTD.;
EMCURE PHARMACEUTICALS USA,
INC.; EMCURE
PHARMACEUTICALS, LTD.;
HOSPIRA, INC.; PHARMACEUTICS
INTERNATIONAL INC.; SAGENT
PHARMACEUTICALS, INC.;
ACS DOBFAR INFO S.A.; STRIDES,
INC.; AGILA SPECIALTIES PRIVATE
LTD.; SUN PHARMA GLOBAL FZE;
CARACO PHARMACEUTICAL
LABORATORIES, LTD.; SUN
PHARMACEUTICAL INDUSTRIES
LTD.; WOCKHARDT USA
LLC; and WOCKHARDT LTD.,

and

ACCORD HEALTHCARE INC.;
FRESENIUS KABI USA, LLC; and
HIKMA FARMACEUTICA S.A.,

Defendants.

Defendants Pharmaceuticals International, Inc., Sagent Pharmaceuticals, Inc., ACS Dobfar Info S.A., Emcure Pharmaceuticals USA, Inc., Emcure Pharmaceuticals, Ltd., Sun Pharma Global FZE, Caraco Pharmaceutical Laboratories, Ltd., and Sun Pharmaceutical Industries Ltd. (“Defendants”) submit supplemental authority in support of their Motion to Dismiss Count II of the Corrected Amended Complaint (Dkt. Nos. 208 and 209 in Case No. 13cv1028).

On March 1, 2013, Novartis filed a Citizen’s Petition with the FDA seeking to block approval of any generic Reclast ANDA having a section viii statement carving out the osteoporosis indications. On March 29, 2013, the FDA implicitly denied Novartis’s Citizen’s Petition when it approved certain Defendants’ generic Reclast ANDAs. On August 1, 2013, the FDA formally denied Novartis’s Citizen’s Petition. (FDA Letter Decision, Exhibit A attached hereto.) In denying Novartis’s petition, the FDA explained in detail the applicable statutory scheme and confirmed that Defendants’ generic Reclast ANDAs containing section viii statements carving out the osteoporosis indications are entirely appropriate and consistent with Congressional intent.

To the extent there is any ambiguity regarding the appropriateness of Defendants’ section viii statements in the context of the Defendants’ motions to dismiss (and Defendants contend there is not), the Court should give deference to the FDA’s decision on the issue. *Cf. Chevron U.S.A., Inc. v. Natural Resources*

Defense Council, Inc., 467 U.S. 837, 844 (1984) (“We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations has been consistently followed by this Court”) (internal quotations and citations omitted).

Dated: September 4, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on 4 September 2013, I caused to be electronically filed the foregoing DEFENDANTS' SUBMISSION OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF THEIR MOTION TO DISMISS COUNT II OF THE CORRECTED AMENDED COMPLAINT with the Clerk of Court via CM/ECF. Notice of this filing will be sent by email to all parties by operation of the Court's electronic filing systems. Parties may access the filing through the Court's CM/ECF System.

/s/ Philip L. Hirschhorn